BB-303
TXR-4265
1/11/80

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY 004265

DATE: January 11, 1980

SUBJECT: EPA File Symbol 464-LLU
Garlon 4 Herbicide; Caswell ~~#883-AD~~ 882I

FROM: Sherell A. Sterling 1-23-80
FHB/TSS E 1/24/80

TO: Robert Taylor
Product Manager (25)

Applicant: Dow Chemical Company
P.O. Box 1706
Midland, MI 48640

Active Ingredient:
Triclopyr.....61.6%
Inert Ingredients.....38.4%

Background: The data in Accession No. 241358 were submitted in support of the conditional registration of Garlon 4. Included in this submission are Acute Oral, Acute Dermal, Eye and Skin Irritation studies on the formulated product. The method of support has not been chosen. The testing was done at Dow's Midland, Michigan laboratories.

Recommendations:

1. The Acute Oral, Acute Dermal and Eye Irritation studies are adequate and acceptable for conditional registration purposes.

2. An Acute Inhalation test was not submitted for this formulation. Such a study or justification for not conducting the study should be submitted. Please see §163.81-3 of the Proposed Guidelines for Human Hazard Evaluation for an outline of acceptable testing and reporting procedures.

3. The Skin Irritation studies conducted on the rabbit abdomen are acceptable; however, the rabbits received challenges on three consecutive days rather than the preferred 24-hour exposure. The Skin Irritation study conducted on the rabbit ears is Core Supplementary Data. Please see the Proposed Guidelines for further information.

4. Based on the acute toxicology data thus far submitted, the appropriate signal word is CAUTION.

5. FHB/TSS has no objection to the conditional registration of this product provided that an Acute Inhalation study or justification for not conducting such a study is submitted and the following labeling revisions are made.

1985

EPA FORM 1320-6 (REV. 3-76)

Labeling:

1. The signal word should be changed to CAUTION.

2. The precautionary statements should be revised to the following or similar statements:

   Avoid contact with skin, eyes or clothing.
   Harmful if swallowed. Avoid breathing vapors.

3. The practical treatment under "In case of contact" should be revised to the following or similar statement and should follow the eyewash statement:

   Get medical attention if
   irritation persists.

Review:

1. Acute Oral Toxicity; Dow Toxicology Research Lab; June 23, 1975

   Procedure: Groups of 5M, 5F
   Sprague - Dawley rats received oral dosages of 252, 500, 1000, 2000 and 3980 mg/kg of Garlon 4. Animals were observed for 14 days post-treatment.

   Results: At 252, 500 and 1000 mg/kg there were no deaths. At 2000 mg/kg, 1/5M and 2/5F died. At 3980 mg/kg, all animals died. Symptoms included lethargy, diarrhea, loss of balance and piloerection. All surviors gained weight. LD50 for males is 2460 mg/kg with a 95% confidence range of 1880-3230; LD50 for females is 2140 with a 95% confidence raange of 1540-2990 mg/kg.

   Study Classification: Core Minimum Data. No necropsies were performed.

   Toxicity Category: III - CAUTION

2. Acute Percutaneous Absorption; Dow Toxicology Research Lab.; June 23, 1975

   Procedure: 2M, 2F New Zealand white rabbits, all with abraded skin, received an application of 3980 mg/kg of Garlon 4. Exposure was for 24 hours under occlusive wrap. Animals were observed for 14 days.

   Results: No mortalities. Symptoms include moderate erythema, severe edema and very slight to slight necrosis.

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Study Classification: Core Minimum Data. No necropsies were performed. Only 4 animals tested.

Toxicity Category: III - CAUTION

3. Eye Irritation; Dow Toxicology Research Lab.; June 23, 1975

Procedure: 0.1 ml of Garlon 4 was applied into both eyes of each of 6 New Zealand white rabbits, one eye of each animal was then irrigated. Irrigation was for 2 minutes with tepid tap water starting 30 seconds post-treatment. Scoring at 24, 48, 72 hours and 7 days.

Results: No irritation observed.

Study Classification: Core Guideline Data.

Toxicity Category: IV - CAUTION

4. Skin Irritation; Dow Toxicology Research Lab.; June 23, 1975

Procedure: 0.5 ml of Garlon 4 was appplied to each of 6 New Zealand white rabbits for 3 consecutive days. Exposure was to abraded and intact sites on the abdomen under occlusive wrap. Also, exposure was to the rabbit ears.

Results: At 24 hours, no irritation was observed on the ears. On the abdomen at 24 hours, slight erythema was observed on the intact and abraded sites; slight edema at 2 abraded sites. By 72 hours, slight to moderate erythema on 5/6 rabbit ears. Slight erythema in 6/6 intact sites at 72 hours; abraded sites showed 6/6 with slight to moderate erythema and 1/6 with slight edema.

Study Classification: Core Minimum Data. Scoring scale must be included with data. Application made on 3 consecutive days. Data on ear applications not necessary.

Toxicity Category: III - CAUTION